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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,081	11/16/2000	Joaquin Villalobos	CRD-726	5133

7590

06/02/2003

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 06/02/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

EE

Office Action Summary

Application No.

09/714,081

Applicant(s)

VILLALOBOS ET AL.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2002 and 24 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 23, 2002 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 is in a format reciting a combination-subcombination. The combination being the delivery apparatus, and the subcombination being the stent. The preamble recites "A delivery apparatus for a self-expanding stent", suggesting the stent is not part of the delivery apparatus. The scope differs within the claim, wherein the scope of the preamble is a delivery apparatus and the scope of the body claim part c is a stent structure. Patentable weight will not be given to stent structure unless the preamble scope is changed to for example --A stent delivery system comprising-- or --A stent delivery apparatus comprising--.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen (USPN 5,324,304, cited in previous office action) in view of Palestrant (USPN 4,832,055, cited in first office action). Referring to claims 1, 4, and 13, Rasmussen discloses a delivery apparatus comprising an outer sheath (5), an inner shaft (8, 10) coaxially positioned within the sheath (5), wherein the inner shaft (8) further comprises at least two grooves (14), and a self-expanding stent (1; col.1, lines 5-10) having at least two legs (2) attached to the proximal end of the stent, extending proximally, each leg having a flange (4), wherein flanges (4) are set within grooves (14) releasably attaching the stent (1) to the shaft (8, 10). Rasmussen does not disclose however, a stop releasable affixed to the inner shaft. Palestrant teaches in the same field of self-expanding stent delivery apparatus, attaching a releasable affixed stop (291) to the exterior surface of an inner shaft (280), the stop having an outer diameter larger than an inner diameter of an outer sheath (270) in order to define a fixed space and limit movement between the outer catheter and stop, allowing a predetermined amount of partial deployment (col.15, line 62- col.16, line 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Palestrant's teaching of use of a releasable stop member on an inner shaft of a delivery apparatus, with the stent delivery apparatus of Rasmussen in order to allow a predetermined amount of partial deployment.

Referring to claim 5, Rasmussen discloses a self-expanding stent, however does not explicitly disclose the material the stent is made of. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the self-expanding stent out of superelastic Ni-Ti alloy, a

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known self-expanding material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Referring to claim 7, Rasmussen discloses flanges (4) that fit completely within the grooves (14), (col.2, lines 30-32; col.4, lines 29-34; col.5, lines 49-54).

Referring to claims 8 and 10, Rasmussen discloses legs that are equally spaced apart and extend distally and axially away from the self-expanding stent (fig.4, 6, 8).

Referring to claims 6, 9, and 11, Rasmussen discloses legs having bent L-shaped flanges and line slit grooves in the inner shaft. Rasmussen does not disclose expressly I or T shaped flanges or grooves. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to create an I or T shaped groove/flange because Applicant has not disclosed that an I or T shaped flange or groove provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with L shaped flanges/grooves because any flange will fit within a corresponding groove providing a low profile diameter, regardless the shape of the flange/groove. Therefore, it would have been an obvious matter of design choice to modify Rasmussen to obtain the invention as specified in claims 6, 9, and 11.

Claims 2, 3, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen (USPN 5,324,304, cited in previous office action) in view of Palestrant (USPN 4,832,055, cited in a previous office action) as applied to claims 1 and 4 above, and in further view of Johnson et al. (USPN 6,136,006, cited in previous office action). Rasmussen discloses a self-expanding delivery apparatus and Palestrant teaches the use of a releasably affixed stop member (291) on the delivery apparatus (figs.11-15; col.15, line 62- col.16, line 15). Palestrant does not however, clearly show the details of the shape of the stop or how exactly the stop is releasably affixed to the catheter. Johnson teaches in the same field of

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delivery apparatus and stop members, a releasably affixed stop member (76) that is semi-cylindrical and snap fits over an inner shaft (26), providing a means for removal of the stop (col.7, lines 1-3), and the stop having an outside diameter larger than an inner diameter of an outer shaft (18) so that the outer sheath abuts the stop, limiting the amount of movement of the outer sheath (18) relative to the inner catheter (26; col.6, lines 63-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Johnson's teaching of specific size and snap fit shape for a stop member with the stent delivery apparatus with releasable stop member of Rasmussen in view of Palestrant's in order to provide a means for limiting the amount of movement of an outer sheath relative to an inner catheter when the stop is affixed and provide a means for removal of the stop, at the time of full deployment.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl Miller

May 22, 2003

BRUCE SNOW
PRIMARY EXAMINER